Intensity-Modulated Radiotherapy (IMRT)

RETIRED 5/11/2017

Policy Number: 2015M0075A  Effective Date: April 01, 2015

Table of Contents:

<table>
<thead>
<tr>
<th>Policy Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coverage Rationale/clinical Considerations</td>
<td>2</td>
</tr>
<tr>
<td>Background</td>
<td>4</td>
</tr>
<tr>
<td>Regulatory Status</td>
<td>4</td>
</tr>
<tr>
<td>Clinical Evidence</td>
<td>5</td>
</tr>
<tr>
<td>Applicable Codes</td>
<td>6</td>
</tr>
<tr>
<td>References</td>
<td>7</td>
</tr>
<tr>
<td>Policy History/Revision Information</td>
<td>11</td>
</tr>
</tbody>
</table>

Cross Reference Policy:

- Radioactive Microspheres Embolization For Treatment of Malignant Tumors, 2014M0072A
- Proton Beam Radiation Therapy, 2013M0022A
- Radium-223 Dichloride (Xofigo®), 2014M0063A

INSTRUCTIONS:

“Medical Policy assists in administering UCare benefits when making coverage determinations for members under our health benefit plans. When deciding coverage, all reviewers must first identify enrollee eligibility, federal and state legislation or regulatory guidance regarding benefit mandates, and the member specific Evidence of Coverage (EOC) document must be referenced prior to using the medical policies. In the event of a conflict, the enrollee's specific benefit document and federal and state legislation and regulatory guidance supersede this Medical Policy. In the absence of benefit mandates or regulatory guidance that govern the service, procedure or treatment, or when the member's EOC document is silent or not specific, medical policies help to clarify which healthcare services may or may not be covered. This Medical Policy is provided for informational purposes and does not constitute medical advice. In addition to medical policies, UCare also uses tools developed by third parties, such as the InterQual Guidelines®, to assist us in administering health benefits. The InterQual Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. Other Policies and Coverage Determination Guidelines may also apply. UCare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary and to provide benefits otherwise excluded by medical policies when necessitated by operational considerations.”
POLICY DESCRIPTION:

This policy discusses the use of Intensity-Modulated Radiation Therapy (IMRT) for the treatment of tumors, both benign and malignant as an alternative to conventional external beam radiation therapy.

COVERAGE RATIONALE / CLINICAL CONSIDERATIONS:

Intensity-Modulated Radiotherapy (IMRT) as a treatment for primary tumors may be considered MEDICALLY NECESSARY to reduce morbidity and avoid damage to critical structures adjacent to the cancer in any of the following situations:

1. The same or an immediately adjacent target lesion has been previously irradiated, and the dose distribution within the patient must be sculpted with high precision to avoid exceeding the cumulative tolerance radiation dose of nearby normal tissue, OR
2. Gross tumor volume (GTV) margins are in close proximity to critical structures which must be protected to avoid unacceptable morbidity and radiation exposure, OR
3. When only IMRT techniques would decrease the probability of grade 2 or grade 3 radiation toxicity as compared to conventional radiation.

Note: IMRT is not a replacement therapy for conventional and 3-D conformal radiation therapy methods. IMRT is considered reasonable and necessary in instances where accurate delineation to maximize radiation dose to the target tumor is important, and the sparing of the surrounding normal tissue is essential.

When any of the situations above are met, IMRT is considered MEDICALLY NECESSARY for treatment of patients with radiosensitive malignancies for any of the following (this is not an all-inclusive list):

- Breast cancer with close proximity to critical structures;
- Brain, including metastatic cancer of the brain and spinal cord;
- Central nervous system tumors with close proximity to the optic nerve or brain stem;
- Primary head and neck cancer of the following areas: pharynx, larynx, salivary glands, oral cavity, nasal cavity, paranasal sinuses, and eye;
- Prostate cancer;
- Anal cancer;
- Primary or benign bone tumors;
- Cervical cancer in patients who have had a hysterectomy; • Esophageal cancer and gastro-esophageal (GE) Junction;
Intensity-Modulated Radiotherapy is considered EXPERIMENTAL and INVESTIGATIONAL for the following diagnoses:
- Colon cancer;
- Cancers of unknown primary source;
- All diagnoses that do not meet the above criteria.

Due to inadequate clinical evidence of safety and/or efficacy in published, peer-reviewed medical literature, comparative effectiveness studies, including randomized controlled trials, are needed to demonstrate the safety and long-term efficacy of this technology.

**Clinical Considerations:**

- **Prostate carcinoma:** Treatment of primary prostate carcinoma may be indicated in the following situations:
  1. Ultra high dose radiation (dosage of 75 Gy or more - 1 Gy = 100 rads) is planned on a patient with intact prostate and non-metastatic prostate cancer.
  2. As adjuvant/salvage therapy after radical prostatectomy in patients with adverse pathologic features or detectable PSA, and no evidence of disseminated disease.
  3. Symptomatic, metastatic prostate cancer when the target disease is within, or immediately adjacent to, previously irradiated tissue.
  4. Selected cases of solitary metastatic lesions.

- **Breast cancer:** Breast cancer with close proximity to critical structures (would need to be reviewed on an individual basis). Information regarding the following factors should be considered and documented to support the indication of breast cancer for IMRT:
  1. Breast size;
  2. Proximity of cardiac structures (for left sided disease);
  3. Nodal involvement;
  4. Reconstruction/prostheses;
  5. Unusual body habitus or anatomy, which requires advanced techniques to reduce normal tissue toxicity;

- **Lung cancer:** Treatment for non-small cell lung cancer may be considered in limited situations only, in which the tumor is fixed to the vertebral body, located at the superior sulcus or involving bilateral mediastinum, to avoid over dose of radiation to normal tissues.

- **Gastric cancer:** Including cancer in the proximal 5cm of the stomach, to reduce dose to normal structures such as heart, lungs, kidneys and liver.
**Pancreatic adenocarcinoma:** Treatment for pancreatic cancer may be considered in the following situations:

1. Applied in the adjuvant setting with the aim of increasing radiation dose to the gross tumor/tumor bed while minimizing toxicity to surrounding tissues.
2. Given with or without 3D-conformal with breath holding/gating techniques for improved planning target volume (PTV) coverage and decreased dose to organs at risk (OARs).

**Contraindications:** No contraindications to IMRT were identified in the available literature. IMRT requires expertise and careful target design to avoid reduction in local control by so-called “marginal miss.” Specific protocols are referenced in the guidelines (NCCN, Clinical Practice Guidelines in Oncology, Anal Cancer 2015).

**BACKGROUND:**

Intensity-modulated radiation therapy (IMRT) is a form of three-dimensional conformal radiation therapy (3D CRT). Three-dimensional conformal radiation therapy uses advanced computer technology to tailor the radiotherapy beam to the exact size and shape of a tumor, while minimizing incidental irradiation of surrounding normal tissues. Using 3D-CRT allows delivery of higher doses of radiation to the site than would be possible with conventional external beam radiation therapy, with the objective of improving local control and, ultimately, survival. Intensity-modulated radiation therapy combines two advanced concepts to deliver 3D-CRT to tumors at the higher dosages with enhanced precision: (1) inverse treatment planning with optimization by computer; and (2) computer-controlled intensity modulation of the radiation beam during treatment.

Treatment planning with IMRT begins with simulation. Simulation involves computed tomography (CT), which may be coregistered with diagnostic CT, magnetic resonance imaging (MRI), or positron emission tomography (PET) scans. The images from these scans are used to estimate the gross tumor volume (GTV), to delineate the organs at risk (OARs), and to determine the clinical tumor volume (CTV; the GTV plus a margin), the planning target volume (PTV; the CTV plus a margin), the radiation dose to the PTV, and the radiation dose constraints to nearby structures. IMRT usually is planned in reverse (inverse planning), which begins with setting the desired clinical objectives for the GTV, CTV, and nearby normal tissues. Once these objectives are specified, an algorithm determines the beam parameters that will yield the desired dose distributions.

**REGULATORY STATUS:**

1. **U.S. FOOD AND DRUG ADMINISTRATION (FDA):** IMRT for colon cancer is a procedure and, therefore, not subject to FDA regulation. However, devices used in a medical procedure require FDA approval. The FDA has approved an extensive variety of radiotherapy treatment planning systems (product code MUH), LINACs (product code IYE), and accessories (product code IYE or LHN) that are appropriate for IMRT. Each can be searched in the Premarket Notification (PMN) Database by their respective product codes.
The FDA has approved a number of devices for use in conformal radiation therapy, including several linear accelerators, beam-shaping blocks, and multileaf collimators. Examples of approved devices and systems are the NOMOS Slit Collimator (BEAK™) (NOMOS Corp.), the Peacock™ System (NOMOS Corp.), the Varian Multileaf Collimator with dynamic arc therapy feature (Varian Oncology Systems), the Saturne Multileaf Collimator (General Electric Co.), the Mitsubishi 120 Leaf Multileaf Collimator (Mitsubishi Electronics America, Inc.), the Stryker Leibinger Motorized Micro Multileaf Collimator (Stryker Leibinger), the Mini Multileaf Collimator, model KMI (MRC Systems GMBH), and the Preference IMRT Treatment Planning Module (Northwest Medical Physics Equipment, Inc.) (FDA, 1996; FDA, 1997a; FDA, 1997b; FDA, 1998a; FDA, 1998b; FDA, 2000; FDA, 2001; FDA, 2002).

2. CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS):
   National Coverage Determination (NCD):
   Medicare does not have a NCD for intensity-modulated radiation therapy (IMRT) for the treatment of tumors. In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

   Local Coverage Determination (LCD):
   National Government Services (NGS) does not have a LCD for IMRT.

3. MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS): Minnesota DHS does not have a policy statement regarding IMRT for the treatment of tumors in its Provider Manual or other specific provider references.

CLINICAL EVIDENCE:
Intensity-modulated radiation therapy has been studied for the treatment of various primary tumors.

SUMMARY:
Breast: There is evidence of very low quality that accelerated partial breast irradiation (APBI) delivered by three-dimensional conformal radiation therapy (3D-CRT) or intensity-modulated radiation therapy (IMRT) is feasible, has mild to moderate toxicity, and results in acceptable cosmesis for patients with early-stage breast cancer who have undergone breast-conserving surgery (BCS). However, the findings from three studies suggest potentially unacceptable toxicity or cosmesis. Nearly all of the available evidence was derived from prospective uncontrolled studies; therefore, the clinical benefit of APBI delivered by 3D-CRT or IMRT relative to whole breast irradiation (WBI), the standard care, is unknown.

There is evidence of very low to low quality from controlled and uncontrolled studies that whole breast irradiation (WBI) by intensity-modulated radiation therapy (IMRT) using standard fractionation schedules has lower rates of acute toxicity than standard two-dimensional (2D) radiation therapy in patients with early-stage breast cancer. WBI by IMRT has mild to moderate acute toxicity levels and a low incidence of severe acute toxicity. The evidence was inconsistent regarding the effect of IMRT by standard fractionation on late toxicities and cosmesis. Limited evidence of very low quality was available for the delivery of WBI...
using IMRT on an accelerated hypofractionated schedule or IMRT given on a hypofractionated simultaneous-integrated boost schedule.

**Central nervous system:** The published evidence is limited mainly to feasibility studies of IMRT for malignant glioma including 1 open, nonrandomized comparison and 8 case series. IMRT did not improve time to disease progression compared with conventional EBI, however in all studies, IMRT was well tolerated with few major adverse effects and no late toxicity. In the absence of data from well-designed randomized controlled trials, the shorter treatment duration (2 or 4 weeks versus 6 weeks or longer) and the possible reduction in toxicity of IMRT compared with EBI may provide some palliative benefits for these patients who have a limited life expectancy.

**Head and neck:** An assessment by the Belgian Health Care Knowledge Center (KCE) (Van den Steen et al, 2007) stated the highly accurate irradiation achievable using IMRT is appropriate for treatment of head and neck cancer because organ motion is practically absent. The report found a benefit of IMRT over use of 3DCRT for the sparing of organs, such as salivary glands and the optic nerve. It can be concluded that wellperformed IMRT can improve quality of life (e.g., less xerostomy) in head and neck cancer patients. There are, however, no robust data comparing IMRT with 3D-CRT with regard to relapse or survival.

**Sinus:** The available evidence shows that postoperative IMRT achieves adequate local control with acceptable toxicity in a high percentage of patients with sinus cancer and may benefit health outcomes,
although the overall quality of the evidence is low.

**Prostate:** A low to moderate level of evidence regarding the safety and efficacy of IMRT from one relatively small RCT and several prospective studies suggested that this complex form of conformal radiation therapy may permit the delivery of higher doses of radiation to the prostate with relatively little toxicity to surrounding tissues. There was some early evidence that higher radiation doses resulted in improved local tumor control, biochemical outcomes, and biopsy findings. However, the evidence was insufficient to determine whether IMRT is equal or superior to conventional radiation therapy or 3D-CRT and who would benefit most from this treatment.

**Colon:** No studies on the use IMRT for the treatment of colon cancer were identified.

**Anal:** Multiple pilot studies have demonstrated IMRT reduces toxicity while maintaining local control.

**Bone:** NCCN guidelines for bone cancer state that specialized radiation therapy techniques, such as IMRT, should be considered as indicated in order to allow high-dose therapy while maximizing normal tissue sparing.

**Cervical:** IMRT has not been tested prospectively and is not recommended for the routine treatment of advanced cervical cancer at this time due to significant organ motion issues. However, IMRT may be appropriate to reduce acute toxicities in patients who have had a hysterectomy.

**Esophageal:** Retrospective studies comparing 3D conformal versus IMRT for patients with esophageal cancer have generally shown superior dose conformity and homogeneity with IMRT and reduction of radiation dose to the lungs and heart.

**Pancreatic:** The preliminary evidence suggested that 3D-CRT and IMRT are associated with poor survival, although comparable or marginally better than published rates of median survival following conventional external beam radiation therapy and chemotherapy. Reports on local tumor control for pancreatic cancer were conflicting.

### APPLICABLE CODES:

The Current Procedural Terminology (CPT®) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other medical policies and coverage determination guidelines may apply.

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>G6015</td>
<td>Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session</td>
</tr>
<tr>
<td>G6016</td>
<td>Compensator-based beam modulation treatment delivery of inverse planned treatment using 3 or more high resolution (milled or cast) compensator, convergent beam modulated fields, per treatment session</td>
</tr>
<tr>
<td>G6017</td>
<td>Intra-fraction localization and tracking of target or patient motion during delivery of radiation therapy (e.g., 3D positional tracking, gating, 3D surface tracking), each fraction of treatment</td>
</tr>
<tr>
<td>ICD-9 Codes</td>
<td>Description</td>
</tr>
<tr>
<td>------------</td>
<td>-------------</td>
</tr>
<tr>
<td>V58.0</td>
<td>Encounter for radiotherapy</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-10 Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>D000</td>
<td>Beam Radiation/Brain</td>
</tr>
<tr>
<td>D001</td>
<td>Beam Radiation/Brain Stem</td>
</tr>
<tr>
<td>D0Y0</td>
<td>Other Radiation/Beam</td>
</tr>
<tr>
<td>D006</td>
<td>Beam Radiation/Spinal Cord</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>77301</td>
<td>Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications</td>
</tr>
<tr>
<td>77338</td>
<td>Multi-leaf collimator (MLC) device(s) for intensity modulated radiation therapy (IMRT), design and construction per IMRT plan</td>
</tr>
<tr>
<td>77385</td>
<td>Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; simple</td>
</tr>
<tr>
<td>77386</td>
<td>Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; complex</td>
</tr>
<tr>
<td>77387</td>
<td>Guidance for localization of target volume for delivery of radiation treatment delivery, includes intrafraction tracking, when performed</td>
</tr>
<tr>
<td>77520</td>
<td>Proton treatment delivery; simple, without compensation</td>
</tr>
<tr>
<td>0073T</td>
<td>Compensator-based beam modulation treatment delivery of inverse planned treatment using 3 or more high resolution (milled or cast) compensator convergent beam modulated fields, per treatment session</td>
</tr>
<tr>
<td>77418</td>
<td>Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session</td>
</tr>
</tbody>
</table>

CPT® is a registered trademark of the American Medical Association.

**REFERENCES:**

20. Fang, FM, Chien, CY, Tsai, WL, et al. Quality of Life and Survival Outcome for Patients With Nasopharyngeal


of intensity-modulated radiation therapy for pediatric malignancies.


POLICY HISTORY:

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>02/16/2015</td>
<td>New Policy 2015M0075A. Reviewed and approved by the Medical Policy Committee.</td>
</tr>
<tr>
<td>02/26/2015</td>
<td>Reviewed and approved by the Quality Improvement Advisory and Credentialing Committee (QIACC).</td>
</tr>
<tr>
<td>03/01/2015</td>
<td>Published to ucare.org</td>
</tr>
</tbody>
</table>
| 07/01/2015 | Policy Update:  
  - Added applicable ICD-10 codes to the Coding Section. The list of codes may not be all-inclusive and does not denote coverage.           |